

Compensatory Issues in Clinical Trials : An Ethical Review

1

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Compensatory Issues in Clinical Trials : An Ethical Review

2

- Introduction
- Compensatory Issues in Clinical Trails
- Ethical Concerns with Compensation
- Needs of Future
- Practical Ethical Considerations
- Conclusion

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Compensatory Issues in Clinical Trials : An Ethical Review

3

- Pain, physical disability, or even death is sometimes heard when human subjects participate in biomedical research.
- Of **1600 deaths** that were reported last 3 year, **26 cases** were related to drug concern, there is evidence that compensation was given in just **22** cases.
- Increasing number of clinical trial deaths — 137 deaths registered in 2007, 288 in 2008 and 688 in 2009 & 2010 — is turning regulatory monitoring increasingly important.

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Conflicts of Interest : In Clinical Trials

4

- Financial and non-financial conflicts of interest are a growing concern in clinical research
 - Compensation to subjects
 - Payment of investigators
 - Authorship on papers
 - Publication of negative results
 - Financial interests of institutions.



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Compensation

5

“Research subjects who suffer physical injury in a trial entitled to financial / other assistance to compensate them equitably for any temporary or permanent impairment or disability subject to confirmation from IEC”

Compensatory Issues

6

- The problem with this issue is not about conduct of clinical trials, but to fill the gap or implement a proper system.
- Wherein Sponsor / Study Institute ensures that in event of study related injury or death, subjects are properly and timely compensated.
- Lack of Legal competence to handle such issues and thus there is an urgent need for a dedicated legal authority.

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Conti...

7

- Regulatory authorities generally looked only at the final outcome of the trial (efficacy and/or safety) while approving a drug for marketing and depends on ECs to look at individual patient safety
- Upto what extent IECs should play role in ensuring that serious adverse events are managed efficiently by the Investigator both medically and financially

Conti...

- Investigators depends on sponsors to make provisions for potential compensation claims in clinical trials and many investigators are unaware of the details of the provisions.
- Insurance is an important mechanism as a cover for the payment for research related injuries. Often the format come from abroad and these are modified according to local needs of the sponsor.

Conti..

- The research participants or his relatives has to prove that the injury sustained is because of the research procedure/ medicament.
- Is it required for the subject to pay first and then be compensated after providing proof of such payment?
- Worry with Children's and unconscious patients do not provide their own consent. Money could sway parental or LAR decision making.

Conti...

10

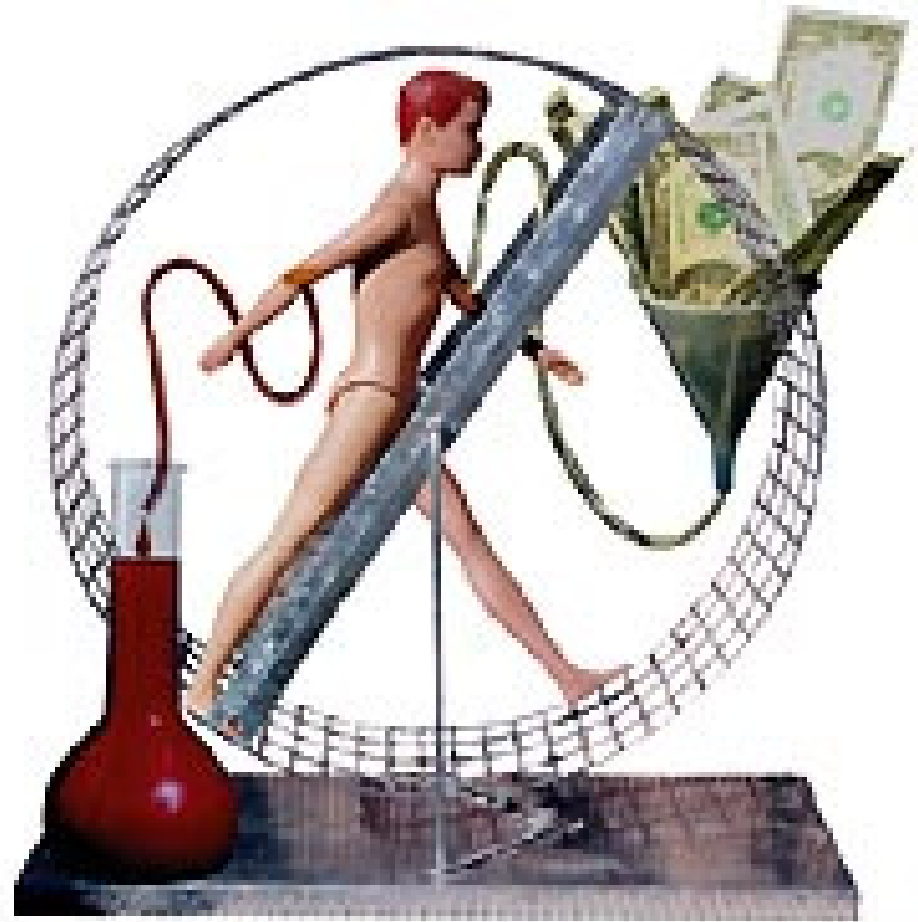
- Some ICD includes Absurd Statements on compensation, for example:
 - “Compensation will be given only if the patient is not covered by his medical insurance policy”
 - Compensation according to guidelines.
 - “that compensation will be provided in accordance with Indian law”

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To pay or not to pay research participants? Ethical Concerns

11

- Commodification
- Skewed sample
- Coercion
- Undue inducement



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Skewed sample

12

- Worry: Money more attractive to lower income individuals

- Results
 - ▣ A skewed sample

- DATA???
 - ▣ Who participates in research?

Coercion or undue influence?

13

- Coercion is a threat of physical, psychological, or social harm in order to compel someone to do something, such as participate in research.
- US Code of Federal Regulations require that informed consent be obtained “under circumstances...that minimize the possibility of coercion or undue influence”

What is undue inducement ?

14

- An offer one cannot refuse
- A controlling and irresistible influence
- Strong enough to compel someone to participate against their interests



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Why worry about undue influence in Research?

15

- An inducement is undue if it is “...so attractive that it can blind prospective subjects to potential risks or impair their ability to exercise proper judgment”
- “prompt them to lie or conceal information that would disqualify them from enrolling--or continuing--in research”

Needs Of Future

16

- Models for paying research participants...
 - Market model
 - Wage payment model
 - Reimbursement model

Dickert, N and Grady, C. (1999) *NEJM* 341(3):198-203

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Models of payment

17

	Market	Wage Payment	Reimbursement
<i>Justification</i>	Incentives to facilitate recruitment	Compensation for time, effort, uncomfortable procedures	Participation should be revenue neutral
<i>Approach</i>	Escalate payment to meet recruitment	Standardized wage-like payments	Reimbursement of out-of-pocket expenses

Dickert, N and Grady, C. (1999) *NEJM* 341(3):198-203

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Wage Payment Model

18

- Participation in research requires little skill but takes time, effort, and endurance
- Payment should be based on a wage scale similar to other unskilled jobs
- Pay a standardized hourly “wage”, perhaps augmented by pay for particularly uncomfortable procedures or added inconvenience

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Advantages of Wage Payment

19

- Greatly reduces the potential for undue inducement
- Provides valuable standardization across studies
- Adheres to the principle of justice by paying similar individuals similar amounts

Practical Ethical Considerations

20

- Proposal submitted to the IECs should describe rationale for payment, how and when payment will be made.
- IECs should not consider payment a benefit to offset research risks when deciding to approve a study
- Need to stress on mentioning to make a clear statement in ICD regarding risk involved ,about insurance and any other compensation involved in trails.
- Deal strictly with the SAEs .

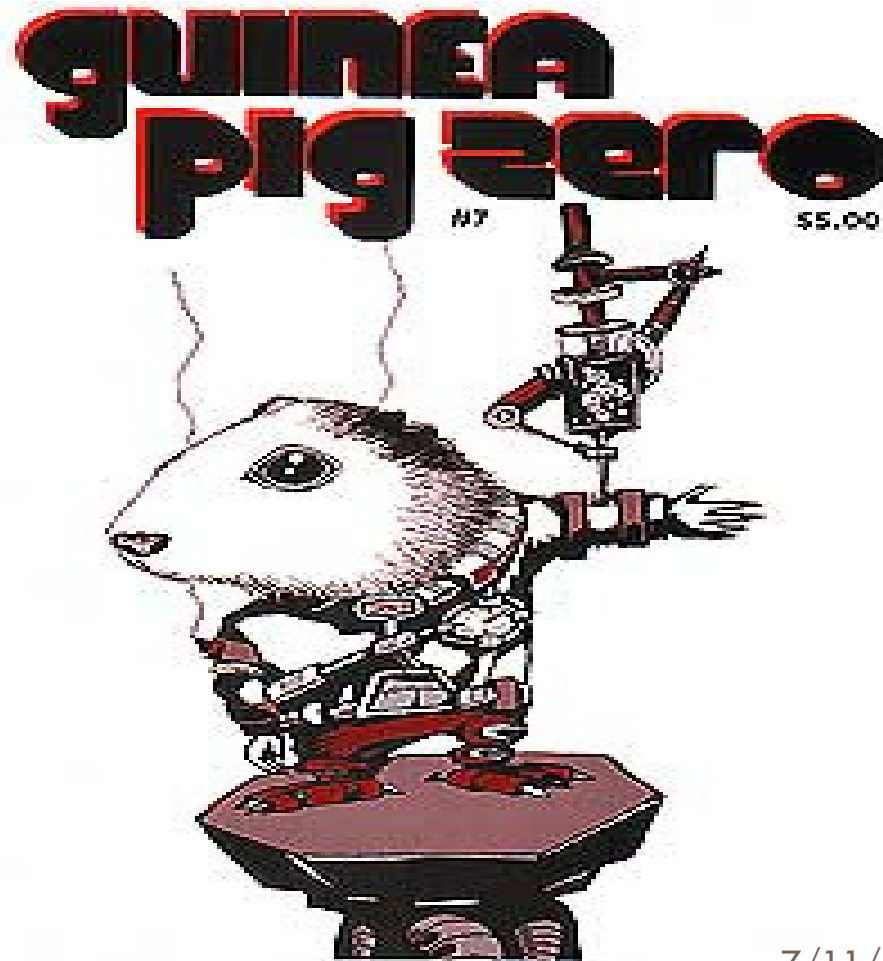
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Conclusion

- ❑ The society as whole seems not well prepared to offer remedy for uncertain risks.
- ❑ No definite scheme seems in position to address compensation for research injuries.
- ❑ Therefore important to observe the further movement of either legal rules or ethical principles in this regard in future

THANK YOU

22



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